

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.

What is claimed is

- Subj 1*
1. A method of treating, preventing or reducing the risk of developing a menopause disorder in a mammal in need thereof, comprising administering to the mammal a menopause disorder effective amount of an orally deliverable pharmaceutically-acceptable sex hormone binding globulin synthesis inhibiting agent, and at least one of a non-orally deliverable pharmaceutically-acceptable steroid.
 2. The method of claim 1 wherein the sex hormone binding globulin synthesis inhibiting agent is methyltestosterone.
 - Subj 2*
3. The method of claim 2 wherein the methyltestosterone is administered in the form of a tablet, capsule, cachet, lozenge, dispensable powder, granule, solution, suspension, emulsion or liquid.
 4. The method of claim 1 wherein the non-orally deliverable steroid is at least one of an androgen or an estrogenic steroid.
 5. The method of claim 4 wherein the androgen is a steroid in the testosterone synthetic pathway.
 6. The method of claim 5 wherein the steroid is at least one of testosterone, androstenedione, androstenediol, dehydroepiandrosterone, prenenolone, and dihydrotestosterone.
 - Subj 4*
7. The method of claim 6 wherein the steroid is testosterone.
 8. The method of claim 7 wherein the androgen is administered percutaneously.
 - Subj 3*
9. The method of claim 8 wherein the androgen is administered in the form of a hydroalcoholic gel.
 - Subj 4*
10. The method of claim 9 wherein the hydroalcoholic gel further comprises at least one of a lower alcohol, a penetration enhancer, and a thickener.

- Sub C*
- Sub E*
- Sub F*
- Sub G*
11. The method of claim 10 wherein the lower alcohol is selected from the group consisting of ethanol, 2-propanol, and mixtures thereof.
 12. The method of claim 10 wherein the enhancer is isopropyl myristate.
 13. The method of claim 10 wherein the thickener is CARBOPOL®.
 14. The method of claim 4 wherein the estrogenic steroid is estradiol.
 15. The method of claim 14 wherein the estrogenic steroid is administered percutaneously.
 16. The method of claim 15 wherein the estrogenic steroid is administered in the form of a hydroalcoholic gel.
 17. The method of claim 16 wherein the hydroalcoholic gel further comprises at least one of a lower alcohol, and a thickener.
 18. The method of claim 17 wherein the lower alcohol is at least one of ethanol, 2-propanol, and mixtures thereof.
 19. The method of claim 18 wherein the thickener is CARBOPOL®.
 20. The method of claim 1 wherein the sex hormone binding globulin synthesis inhibiting agent and the steroid are each provided as a separate component of a kit.
 21. The method of claim 1 wherein the mammal is a human.
 22. The method of claim 1 wherein the sex hormone binding globulin synthesis inhibiting agent and the steroid are administered in a sequential manner.
 23. The method of claim 1 wherein the sex hormone binding globulin synthesis inhibiting agent and the steroid are administered in a substantially simultaneous manner.
 24. The method of claim 1 further comprising at least one of a pharmaceutical agent for treating erectile dysfunction.

- Sub C 1*
25. The method of claim 24 wherein the pharmaceutical agent is at least one of sildenafil citrate, pentoxifylline, yohimbine hydrochloride, apomorphine, alprostadil, papavaerine, and phentolamine.
26. The method of claim 1 where the sex hormone binding globulin synthesis inhibiting agent comprises about 0.2 mg to about 50.0 mg methyltestosterone, the steroid comprises about 0.1 g to about 100.0 g testosterone.
27. The method of claim 26 wherein the mammal achieve hormonal steady state levels of testosterone.
28. The method of claim 1 where the sex hormone binding globulin synthesis inhibiting agent comprises about 0.2 mg to about 50.0 mg methyltestosterone, the steroid comprises about 0.1 g to about 100.0 g estradiol.
- Sub C 8*
29. The method of claim 28 wherein the mammal achieve hormonal steady state levels of estradiol.
30. A kit comprising an orally deliverable sex hormone binding globulin synthesis inhibiting agent and at least one of a non-orally deliverable steroid, wherein the sex hormone binding globulin synthesis inhibiting agent and the steroid together make a menopause disorder effective amount.
31. The kit of claim 30 wherein the sex hormone binding globulin synthesis inhibiting agent is methyltestosterone.
32. The kit of claim 30 wherein the sex hormone binding globulin synthesis inhibiting agent is administered in the form of a tablet, capsule, cachet, lozenge, dispensable powder, granule, solution, suspension, emulsion or liquid.
33. The kit of claim 30 wherein the steroid is administered percutaneously.
34. The kit of claim 30 wherein the steroid is a steroid in the testosterone synthetic pathway.

- ~~RECEIVED
U.S. PATENT AND TRADEMARK OFFICE~~
35. The kit of claim 30 wherein the steroid is selected from the group consisting of testosterone, androstenedione, androstanediol, dehydroepiandrosterone, prenenolone, and dihydrotestosterone.
36. The kit of claim 35 wherein the steroid is testosterone.
37. The kit of claim 36 wherein the testosterone is administered percutaneously.
38. The kit of claim 30 wherein the steroid is an estrogenic steroid.
39. The kit of claim 38 wherein the estrogenic steroid is estradiol.
40. The kit of claim 39 wherein the testosterone is administered percutaneously.
41. The kit of claim 30 wherein the sex hormone binding globulin synthesis inhibiting agent is present in an amount from about 0.2 mg to about 50.0 mg.
42. The kit of claim 30 wherein the steroid is present in an amount from about 0.1 mg to about 100.0 mg.
43. The kit of claim 30 further comprising at least one of a pharmaceutical agent for treating erectile dysfunction.
44. The kit of claim 43 wherein the agent for treating erectile dysfunction is selected from the group consisting of sildenafil citrate, pentoxifylline, yohimbine hydrochloride, apomorphine, alprostadil, papavaerine, and phentolamine.
45. A method of treating, preventing or reducing the risk of developing a menopause disorder in a mammal in need thereof, comprising administering to the mammal in a combination therapy an orally deliverable pharmaceutically-acceptable sex hormone binding globulin synthesis inhibiting agent, and at least one of a non-orally deliverable pharmaceutically-acceptable steroids, wherein the amount of the sex hormone binding globulin synthesis inhibiting agent and the steroid together make a menopause disorder effective amount.
46. The method of claim 45 wherein the sex hormone binding globulin synthesis inhibiting agent is methyltestosterone.

- but CWD*
47. The method of claim 46 wherein the methyltestosterone is administered in the form of a tablet, capsule, cachet, lozenge, dispensable powder, granule, solution, suspension, emulsion or liquid.
48. The method of claim 47 wherein the non-orally deliverable steroid is at least one of an androgen or an estrogenic steroid.
49. The method of claim 48 wherein the androgen is a steroid in the testosterone synthetic pathway.
50. The method of claim 49 wherein the steroid is at least one of testosterone, androstenedione, androstanediol, dehydroepiandrosterone, prenenolone, and dihydrotestosterone.
51. The method of claim 50 wherein the steroid is testosterone.
52. The method of claim 51 wherein the androgen is administered percutaneously.
53. The method of claim 52 wherein the androgen is administered in the form of a hydroalcoholic gel.
54. The method of claim 53 wherein the hydroalcoholic gel further comprises at least one of a lower alcohol, a penetration enhancer, and a thickener.
55. The method of claim 54 wherein the lower alcohol is selected from the group consisting of ethanol, 2-propanol, and mixtures thereof.
56. The method of claim 54 wherein the enhancer is isopropyl myristate.
57. The method of claim 54 wherein the thickener is CARBOPOL®.
58. The method of claim 48 wherein the estrogenic steroid is estradiol.
59. The method of claim 58 wherein the estrogenic steroid is administered percutaneously.
60. The method of claim 59 wherein the estrogenic steroid is administered in the form of a hydroalcoholic gel.
- but CWD*

- Sub C 13*
- 61. The method of claim 60 wherein the hydroalcoholic gel further comprises at least one of a lower alcohol, and a thickener.
 - 62. The method of claim 61 wherein the lower alcohol is at least one of ethanol, 2-propanol, and mixtures thereof.
 - 63. The method of claim 62 wherein the thickener is CARBOPOL®.
 - 64. The method of claim 45 wherein the sex hormone binding globulin synthesis inhibiting agent and the steroid are each provided as a separate component of a kit.
 - 65. The method of claim 45 wherein the mammal is a human.
 - 66. The method of claim 45 wherein the sex hormone binding globulin synthesis inhibiting agent and the steroid are administered in a sequential manner.
 - 67. The method of claim 45 wherein the sex hormone binding globulin synthesis inhibiting agent and the steroid are administered in a substantially simultaneous manner.
 - 68. The method of claim 45 further comprising at least one of a pharmaceutical agent for treating erectile dysfunction.
 - 69. The method of claim 64 wherein the pharmaceutical agent is at least one of sildenafil citrate, pentoxifylline, yohimbine hydrochloride, apomorphine, alprostadil, papavaerine, and phentolamine.

Sub C 14

 - 70. The method of claim 41 where the sex hormone binding globulin synthesis inhibiting agent comprises about 0.2 mg to about 50.0 mg methyltestosterone, the steroid comprises about 0.1 g to about 100.0 g testosterone.

Sub C 15

 - 71. The method of claim 70 wherein the mammal achieve hormonal steady state levels of testosterone.

Sub C 16

 - 72. The method of claim 41 where the sex hormone binding globulin synthesis inhibiting agent comprises about 0.2 mg to about 50.0 mg methyltestosterone, the steroid comprises about 0.1 g to about 100.0 g estradiol.

73. The method of claim 72 wherein the mammal achieve hormonal steady state levels of estradiol.

TOP SECRET//TECHNOLOGY